

MEDB 1.11 Bone Densitometry

SDCR-SMCCB-11-016-R5

3.2 Medical Requirements Overview

TABLE 3.2: MEDICAL REQUIREMENTS OVERVIEW

MEDB# and Title:	MEDB 1.11 Bone Densitometry
Sponsor:	Medical Operations
IPT:	Bone, Muscle & Exercise
Category:	Medical Requirements (MR)
References:	Medical Evaluation Documents (MED) Volume B Section 1.11
Purpose/Objectives:	To track individual skeletal integrity (loss and recovery), particularly with regard to long-duration flight, and to aid in targeting rehabilitation efforts and facilitating a timely re-certification for long duration missions. Data are also pooled and analyzed to aid in assessing the relative efficacy of countermeasures and rehabilitation programs.
Measurement Parameters:	A Lateral spine morphometric scan and Dual-Energy X-ray Absorptiometry (DXA) scans of whole body, hips, spine, heel, and wrist regions.
Deliverables:	Skeletal health report, evaluation of in-flight countermeasures, skeletal recovery postflight with concurrent rehabilitation recommendations.
Flight Duration:	> 30 days
Number of Flights:	All long duration missions
Number and Type of Crew Members Required:	All primary ISS crewmembers.
Other Flight Characteristics:	Pre- and postflight data collection only

3.3 Preflight Training: None**3.4 Preflight Activities****TABLE 3.4: PREFLIGHT ACTIVITIES**

Preflight Activity	Description:	Data collection includes a lateral spine morphometric scan and DXA scans to include a whole body scan and regional scans of both proximal femurs (hips), spine, calcaneus (heel), and wrist. The crewmember removes all metal (jewelry, etc.), dons a pair of cotton medical scrubs, and lies down on the padded scan table. The technician positions the crewmember for each scan. Whole body scans take approximately 15 minutes; spine, hips, heel and wrist scans take approximately 5 minutes each. The scan data are-stored as digital information on the densitometer’s computer; analysis is performed later by the technician and a summary report generated.				
	Schedule:	Duration:	Schedule:	Flexibility:	Personnel Required:	
		DXA Scans 60 min.	AME L-21/18 month; L-180/30 day (As close to launch as feasible)		Lab personnel and Crew	
Ground Support Requirements Hardware/Software	Preflight Hardware:		Preflight Software:		Test Location:	
	Hologic QDR 4500 W DXA Scanner		N/A		U.S.	
Testing Facilities	Minimum Room Dimensions:	Number of Electrical Outlets:		Temperature Requirements:		Special Lighting:
	10’ x 11.5’	2-4 (110V)		Ambient		Ability to dim lights
	Hot or Cold Running Water:	Privacy Requirements:		Vibration/Acoustic Isolation:		Other:
	N/A	Room with controlled access and area for clothes change		N/A		N/A
Constraints/Special Requirements:	1.All female patients presenting for a DXA scan will have a pregnancy test accomplished prior to the DXA scan and the result verified as negative with the following three exceptions: <ul style="list-style-type: none">• The patient no longer has a uterus.• The patient is greater than one year post menopause.• The patient has a documented negative pregnancy test obtained during the three days preceding the DXA scan. 2. All DXAs must be done in the crewmember's home country so that the same machine is used for all data collections. 3. No radioisotopes or radiopaque contrast agents for one week prior to test. Remove all metal (jewelry, etc.). 4. Session requires level 3 medical monitoring.					
Launch Delay Requirements:	One data collection will be repeated if launch is delayed by more than five (5) months. At the very least, two sessions are required within a year of launch, with one of those sessions being within 6 months of launch.					

TABLE 3.4: PREFLIGHT ACTIVITIES (continued)

Notes:	1. Facilities for performing bone densitometry have been established and are currently maintained at NASA/JSC.
Data Delivery	Data/Report to Designated Recipients (Nominal/Contingency):
	Test results will be entered in the Electronic Medical Record. Data will be shared with MEDB 8.1 Nutritional Assessments.

3.5 In-Flight Activities: None

3.6 Postflight Activities

TABLE 3.6: POSTFLIGHT ACTIVITIES

Postflight Activity Description:	Postflight data collection will be completed within the first 30 days of return, and then as clinically indicated to assess BMD recovery (i.e., values are within approximately 2% of baseline). If complete recovery is documented, further measurements will not be obtained until the next scheduled longitudinal measurement or until crewmember is assigned to another long duration mission and begins preflight testing.			
	Duration:	Schedule:	Flexibility:	Personnel Required:
	DXA Scans 60 min.	Within first 30 days of return, then as clinically indicated to assess BMD recovery.	N/A	Lab Personnel and Crew
Schedule:				
Ground Support Requirements Hardware/Software	Postflight Hardware:		Postflight Software:	Test Location:
	Hologic QDR 4500 W DXA Scanner		N/A	U.S.
Testing Facilities	Minimum Room Dimensions:	Number of Electrical Outlets:	Temperature Requirements:	Special Lighting:
	10' X 11.5'	2-4 (110V)	Ambient	Capability to dim lights
	Hot or Cold Running Water:	Privacy Requirements:	Vibration/Acoustic Isolation:	Other:
	N/A	Room with controlled access and area for clothes change	N/A	N/A
Constraints/Special Requirements:	<p>1. All female patients presenting for a DXA scan will have a pregnancy test accomplished prior to the DXA scan and the result verified as negative with the following three exceptions:</p> <ul style="list-style-type: none"> • The patient no longer has a uterus. • The patient is greater than one year post menopause. • The patient has a documented negative pregnancy test obtained during the three days preceding the DXA scan. <p>2. All DXAs must be done in the crewmember's home country so that the same machine is used for all data collections.</p> <p>3. No radioisotopes or radiopaque contrast agents for one week prior to test. Remove all metal (jewelry, etc.).</p> <p>4. Session requires level 3 medical monitoring.</p> <p>5. If landing occurs in Russia, postflight data collection will take place within one week of return to JSC.</p>			
Data Delivery	Data/Report to Designated Recipients (Nominal/Contingency):			
	Test results will be entered in the Electronic Medical Record. Data will be shared with MEDB 8.1 Nutritional Assessments.			

3.7 Summary Schedule

TABLE 3.7: SUMMARY SCHEDULE

ACTIVITY	DURATION	SCHEDULE	FLEXIBILITY	PERSONNEL REQUIRED	CONSTRAINTS
Preflight Training: None					
Preflight Activity					
DXA Scans	60 min.	AME L-21/18 m; L-180/30 d (As close to launch as feasible)		Lab personnel and crew	<p>1. All female patients presenting for a DXA scan will have a pregnancy test accomplished prior to the DXA scan and the result verified as negative with the following three exceptions:</p> <ul style="list-style-type: none"> • The patient no longer has a uterus. • The patient is greater than one year post menopause. • The patient has a documented negative pregnancy test obtained during the three days preceding the DXA scan. <p>2. All DXAs must be done in the crewmember's home country so that the same machine is used for all data collections.</p> <p>3. No radioisotopes or radiopaque contrast agents for one week prior to test. Remove all metal (jewelry, etc.).</p> <p>4. Session requires level 3 medical monitoring.</p>
In-Flight Activity: None					
Postflight Activity					
DXA Scans	60 min.	Within first 30 days of return, then as clinically indicated to assess BMD recovery.	N/A	Lab personnel and crew	Same as preflight